Feasibility Study of a Single-Blind Randomised Controlled Trial of an Occupational Therapy Intervention

Brigitte E. Gantschnig[1,5], PhD, Ingeborg Nilsson[2], PhD, Anne G. Fisher[2,3], ScD, Christoph Künzle[4], MD, Julie Page[1], PhD,
[1]Zurich University of Applied Sciences, School of Health Professions, Institute of Occupational Therapy, Switzerland
[2]Umeå University, Faculty of Medicine, Department of Community Medicine and Rehabilitation, Division of Occupational Therapy, Sweden
[3]Colorado State University, College of Health and Human Sciences, Department of Occupational Therapy, Fort Collins, USA.
[4]Eastern Swiss Children's Hospital St. Gallen, Switzerland
[5]Bern University Hospital Department of Rheumatology, Immunology and Allergology, and University of Bern, Switzerland

Correspondence concerning this article should be addressed to Brigitte E. Gantschnig, Zurich University of Applied Sciences, School of Health Professions, Institute of Occupational Therapy, Technikumstrasse 71, Postfach, CH-8401 Winterthur, Tel: 0041 58 934 63 65 Fax: 0041 58 935 63 65, e-mail: brigitte.gantschnig@zhaw.ch

All authors' e-mail addresses brigitte.gantschnig@zhaw.ch; ingeborg.nilsson@umu.se; Julie.page@zhaw.ch; anne.fisher@innovativeotsolutions.com; christoph.kuenzle@kispisg.ch

Abstract

Background. Several factors facilitate or hinder occupational therapy efficacy research. Strategies are needed, therefore, to support the successful implementation of trials of the effectiveness of occupational therapy.

Aim. To assess the feasibility of conducting a multi-centre, single-blind randomised controlled trial (RCT). The main feasibility objectives of this study were to assess the process, resources, management, and scientific basis of a trial RCT.

Materials and Methods. A total of 10 occupational therapists, between the ages of 30 and 55 (*M* 43.4; *SD* 8.3) with 7 to 26 years (*M* 14.3; *SD* 6.1) experience, participated in this study. Qualitative data collected included minutes of meetings, documentation, children's reports, and field notes. We analysed the data qualitatively, based on the principles of content analysis, using feasibility objectives proposed in the literature as the main categories.

Results. Data analysis revealed strengths in relation to retention and inclusion criteria of participants, the study protocol, the study organisation, and the competence of researchers. Weaknesses were found related to recruitment, randomisation, data collection, time for training and communication, commitment to research, and study design.

Conclusion. The findings indicated that there are several factors that had a considerable impact on facilitating or hindering the implementation of an RCT in occupational therapy practice. However, the feasibility study was useful to assess methods and procedures of the trial RCT as a basis to refine research plans and implement research successfully.

MeSH Keywords : implementation, practice, pilot study

Introduction

There is a need for evaluating the effectiveness of occupational therapy in order to determine whether an intervention has the intended outcome with a specific client group (1-3). Therefore, effectiveness studies are conducted in practice settings, not in standardised environments, and they involve different stakeholders (e.g., clients, occupational therapists, physicians, decision makers) and require various resources (e.g., time, money, facilities) (4, 5). Several factors facilitate or hinder executing full scale trials in practice (e.g., costs, funding, ethics) and, therefore, effective strategies to support their successful implementation are needed (2) internationally, but especially in Switzerland where no effectiveness studies of occupational therapy have successfully been conducted or published to date.

One way to assess the potential for successful realisation of an effectiveness study is to conduct a feasibility study. The term *feasibility study* often is used in the literature interchangeably with the term *pilot study* because the definitions of these concepts are not consistent and the differences between them are very small (6, 7). In a feasibility study, parts of planned larger study are implemented (e.g., two out of four outcomes are tested); and in a pilot study the larger study is implemented in its entirety but on a small scale (8). In this project, we implemented parts of a planned study and, therefore, we will refer to our project as a feasibility study.

With feasibility studies, researchers aim to assess methods and procedures of planned larger studies (6, 7, 9) in order to refine procedures and avoid negative consequences in the larger studies (e.g., threats to the study outcomes) (7, 9, 10). Feasibility studies are not designed to test intervention hypotheses (6-8, 10) or to estimate effect sizes (7). Rather, they address the feasibility of a randomised controlled trial (RCT) plan before investing more money and time into larger trials (6).

Recently, Thabane et al. (9) and Tickle-Degnen (6) summarised the objectives of feasibility studies. These can be grouped under assessment of the process, resources, management, and scientific basis. We used these four objectives as a structure for evaluating the feasibility of a trial RCT within occupational therapy practice. Our long-term aim would be to test the effectiveness of occupational therapy services for children with attention-deficit/hyperactivity disorder (ADHD) and/or developmental coordination disorder (DCD) in a large scale RCT. The purpose of this feasibility study was to assess the feasibility of conducting that trial RCT. The specific objectives of this study were to assess trial RCT based on the objectives of feasibility studies recommended by Thabane et al. (9) and Tickle-Degnen (6). We use the term *trial RCT* to describe the small scale RCT we conducted in order to evaluate the feasibility.

Materials and Methods

Trial RCT _ENREF_6Design

This study was a feasibility study of a multi-centre, single-blind, trial RCT (balanced randomisation [1:1]) with a cross-over design (see Figure 1). We analysed feasibility qualitatively based on the principles of a content analysis (11) with the main categories *process, resources, management,* and *scientific basis (*see *Table 1)* (6, 9). We will first describe the trial RCT based on the CONSORT guidelines for non-pharmacologic interventions (12, 13) in order to provide a context for presenting and understanding the qualitative methods and results of the feasibility study. Then, we will describe the methods of the feasibility study based on the feasibility objectives proposed by Thabane et al. (9) and Tickle-Degnen (6).

The study was approved by the ethics board of the Canton St. Gallen, Switzerland (EKSG 10/008/1B) and registered at the International Standard Randomised Controlled Trial Number Register (ISRCTN), number ISRCTN55222180.

Methods of the Trial RCT: the Context for the Feasibility Study

- ***Trial RCT Participants***

Eligible participants for the trial RCT were children recruited by paediatricians and/or occupational therapists based on the following inclusion criteria: a) were 5 to 9 years of age; b) had been diagnosed by paediatricians within the last 6 months with attention-deficit/hyperactivity disorder (ADHD) and/or developmental coordination disorder (DCD), according to DSM-IV criteria(14); c) had problems, based on parent report, performing activities of daily living (ADL) tasks; d) were eligible for occupational therapy services; and e) whose parents agreed for their children to participate in the study. The exclusion criterion was a diagnosis of a neurological disorder (e.g., traumatic brain injury, cerebral palsy), autism spectrum disorder, other mental disorder (e.g., childhood depression), or intellectual disability. The paediatricians and the occupational therapists who recruited the children were informed verbally and in writing about the study, including the objectives, inclusion and exclusion criteria, and procedures. When the paediatricians or the occupational therapists first met the children and their parents, they informed them about the study and provided them with written invitations describing the research procedures. Demographic data of children enrolled in the trial RCT are shown in *Table 2*.

- ***Trial RCT Settings and Location***

The study took place in Switzerland at a child rehabilitation centre and in six occupational therapy private practices in three Swiss cantons. The child rehabilitation centre provides inpatient and outpatient medical and rehabilitation services for children with various disabilities. The occupational therapy private practices provide outpatient occupational therapy services in the community, at home, and in schools.

- ***Trial RCT Intervention***

After baseline evaluation, participants were randomly assigned to one of the following sequences: AB (occupational therapy intervention phase/"waiting time" control phase) or BA ("waiting time" control phase/occupational therapy intervention phase) (see Figure 1). The intervention process of the trial RCT was based on the principles of the general occupational therapy program based on the Occupational Therapy Intervention Process Model (OTIPM)(15, 16). The OTIPM is a process model that is used by occupational therapists to plan, implement, and evaluate occupation-based and occupation-focused services. The term *occupation-based service* means that occupational therapists engage persons in occupations as their main evaluation or intervention method (e.g., in daily life tasks); the term *occupation-focused service* means that occupational therapists put their immediate focus on occupations (e.g., talking about performance of daily life tasks, improving ability to perform daily life tasks)(16). The OTIPM has increasingly been used for planning and implementing occupational therapy intervention studies (e.g., 17).

We used the OTIPM to design the study protocol that was evaluated in the trial RCT because the OTIPM supports the professional reasoning of occupational therapists as they implement occupation-based and occupation-focused services. For the trial RCT, all occupational therapists who implemented the interventions attended a 3-day OTIPM-training workshop in January 2011 and used the study protocol based on the OTIPM.

The study protocol described what was to occur at each phase of the trial RCT and how it was to be implemented. More specifically, at baseline, the occupational therapists were to inform the children and their parents about occupational therapy in general. The occupational therapists then were to interview the children, their parents, and/or important others (e.g., teachers) with the Canadian Occupational Performance Measure (COPM) (18) to gain knowledge about what the informants perceived to be the child's strengths and problems

when performing ADL tasks. Thereafter, a standardised performance analysis was to be implemented using the Assessment of Motor and Process Skills (AMPS) (19, 20) (see *Outcomes*) where the occupational therapists were to evaluate the child's observed quality of ADL task performance (21). The occupational therapists then were to formulate measurable goals in collaboration with the child, his or her parents, and/or important others, based on the interviews (see section *Outcomes*), the child's and his or her parents' priorities, and the results of the baseline evaluation of observed performance. During the A phase, the intervention was to be focused on enhancing the children's performances of ADL tasks (e.g., preparing a cheese sandwich). Interventions were to be implemented in weekly sessions, 60 minutes each, over 15 weeks. During the B phase, the children were not to receive any intervention. Those who were assigned to the BA sequence were to be provided with the same occupational therapy intervention after the 15 week waiting time phase.

- ***Trial RCT Outcomes***

As outcome measures we selected two assessments based on: a) what is commonly used in Switzerland, and b) tools that emphasise a client-centred view: The AMPS and the COPM. More specifically, client-centeredness was achieved using the AMPS to evaluate performance of self-selected and prioritized tasks identified by the client as target therapy goals during the COPM interview.

Assessment of Motor and Process Skills

The Assessment of Motor and Process Skills (AMPS) was used as the primary outcome measure. The AMPS is an internationally standardised occupation-based and occupation-focused test of a person's quality of ADL task performance (19, 20). There is extensive evidence to support the reliability and validity of the AMPS measures (22), including their validity for use with children with ADHD and/or DCD (e.g., 23) and with persons in Middle

Europe (24). In accordance with the standardised AMPS testing procedures, the child was observed performing two chosen and relevant ADL tasks at baseline, and again after 15 and 30 weeks. Each AMPS observation was videotaped for future scoring by a blinded rater. Scoring of the 36 AMPS items (i.e., smallest observable actions of ADL task performance) is based on the presence and extent of observed increase in physical effort or clumsiness, decrease in efficiency, decrease in safety, or decrease in the need for assistance during the child's ADL task performance. A four-category ordinal scale is used (4 = skilled performance, no problem; 1 = marked skill deficit, severe problem) is used to score each item. After scoring the quality of the child's ADL task performances, the blinded rater entered the child's raw scores into the AMPS software that was used to convert these ordinal item scores into an equal interval linearized ADL motor and an ADL process ability measure, expressed in logits (19, 20). Scoring the AMPS based on observation of videotaped observations is not part of the standardised AMPS administration procedures, but was chosen to ensure blinded rating of the primary outcome measure.

Canadian Occupational Performance Measure

As a secondary outcome measure, the Canadian Occupational Performance Measure (COPM) (18) was used to evaluate perceived occupational performance from the perspectives of the children's parents. The COPM is a client-centred and occupation-focused interview tool that enabled the occupational therapist to learn about changes in the parent's perception of quality and satisfaction with his or her child's occupational performance over time (18). The administration of the COPM started with a semi-structured interview with parents who were asked to identify their children's issues in the areas of self-care, productivity (e.g., schoolwork), and play/leisure. Once the parents had identified any problems with the children's occupational performance, they rated the importance of each identified activity on an ordinal scale that ranged from 1 to 10. From this list of identified problems, the parents

also chose between two and five problems they wished to focus on during the occupational therapy intervention. For each of the problems, the parents then used an ordinal scale, ranging from 1 to 10, to rate their child's current quality of performance and satisfaction with that performance. Higher ratings indicated better perceived quality of performance and satisfaction with the activity. The COPM is the most frequently used outcome measure in paediatric rehabilitation (25, 26) and its validity has been supported by several studies (e.g., 27). In this study, the COPM was administered at baseline, and again after 15 and 30 weeks by the occupational therapists who implemented the intervention with the children. They were, therefore, not blinded to treatment allocation. It was not possible to use blinded raters because the occupational therapists who implemented the interventions needed the data collected during the COPM to set collaborative and client-centered goals for the implemented interventions.

- ***Trial RCT Randomisation***

Independent persons, not otherwise involved in the study and with no detailed information about it allocated children randomly to the AB or BA sequence (see Figure 1)**.** We used this method because the trial RCT involved sequential enrolment and masking of occupational therapists and paediatricians could not be ensured. The use of independent persons for randomisation also avoided recruiter bias. A random block design was used because enrolment of the participants into the trial RCT occurred over an extended period of time (28).

- ***Trial RCT Blinding***

In an intervention study like the trial RCT, it is impossible to blind the children, their parents, paediatricians, or occupational therapists as to group allocation. However, blinding was strictly maintained for the researchers and the AMPS rater. The trial also maintained separation between the blinded AMPS rater and occupational therapists who delivered the interventions and videotaped the AMPS observations. Videotaping also assured that the

blinded AMPS rater did not meet the children at any time. Finally, all researchers, occupational therapists, and paediatricians were kept blinded to trial results during the data collection phase.

Feasibility Study Methods

- ***Feasibility Study Participants***

A purposive sample of occupational therapists was recruited by the fourth author, a paediatrician who had been working with occupational therapists in the region for 15 years. The inclusion criteria for the occupational therapists were: a) a minimum of 3 years of experience in occupational therapy practice, b) knowledge and skills working with children with ADHD and/or DCD and their families, c) experience using standardised outcome measures, d) willingness to participate in the 3-day OTIPM training workshop, and e) willingness to participate in regular meetings with the research team. The occupational therapists differed in age, years of experience in occupational therapy practice, and type of setting where they worked (i.e., at the rehabilitation centre or in private practices). In total, nine occupational therapists participated in this feasibility study and implemented the interventions.

Additionally, one occupational therapist, who served as the blinded rater was recruited based on the following criteria: a) had a minimum of 3 years of clinical experience, b) was a valid and reliable AMPS rater, and c) had no professional or private connection to the other occupational therapists. The blinded rater was not part of the intervention team and was not informed as to which group the participants were allocated. Demographic data for the 10 occupational therapists who participated in the feasibility study (nine who implemented intervention plus the blinded AMPS rater) are shown in Table 2.

- ***Feasibility Study Qualitative Data Collection***

We collected data during the entire feasibility study research process so as to be able to evaluate the feasibility of the trial RCT. The qualitative data consisted of a) minutes of meetings between researchers, paediatricians, and the occupational therapists; b) minutes of telephone meetings; c) e-mails; d) documentation of outcomes and interventions; and e) field notes. Regular 90-minute group meetings between the nine occupational therapists who implemented the interventions and the researchers were held every month. Regular telephone meetings between the first author and individual occupational therapist interveners were held weekly and lasted between 10 and 75 minutes. Face-to-face meetings or e-mail contact with the blinded AMPS rater occurred separately (i.e., without the other occupational therapists) with the first or third author; the face-to-face meetings lasted between 30 and 60 minutes. The aim of all meetings and e-mail contacts was to discuss issues related to the implementation of the study. For example, we discussed how to inform potential participants about the study, how to implement and interpret the AMPS or the COPM, or how to formulate baselines and set goals; or, for the blinded rater, to discuss issues related to how to deal with scoring aspects of performance that were not well captured on the videotapes or data entry into the AMPS software.

We started qualitative data collection with the first meeting with the occupational therapists and ended it with member-check, after termination of the trial RCT. During the final member-check we discussed the emerging data with the occupational therapists. The minutes of face-to-face meetings were thorough, but not written word for word. They were written by the first author, checked by the last author, and distributed to all participants involved in the meetings. Occupational therapists then gave written feedback about the minutes to the first author, and the first author noted any errors or omissions and revised the minutes accordingly. Furthermore, field notes were written after every meeting. The field

notes included first author's reflections (e.g., her experience in her role as a novice researcher) and they were distributed to and discussed with all other authors. Thus, all data were in written format (i.e., no audio data).

- **Feasibility Study Qualitative Data Analysis**

We analysed the written qualitative data based on the principles of content analysis (11) emphasising feasibility of the trial RCT. Therefore, we defined the main categories of our apriori coding frame based on the feasibility objectives proposed by Thabane and colleagues (9) and Tickle-Degnen (6), that is, process, resources, management, and scientific basis of the trial RCT (deductive approach). An example of a leading questions was, "What were the strengths or weaknesses of the process?" Then, we identified subcategories (e.g., recruitment) that specified aspects within each of the four main categories, both deductively in a theory-driven way and inductively in a data-driven way (see Table 3) and coded our data accordingly. An example of a specific question was, "What were the strengths or weaknesses of the planned randomisation process?" During coding, we revised and expanded subcategories (e.g. *low recruitment rate* and *difficulties with randomisation*) by going back and forth between theory and the data. The first author coded the data based on the coding frame on which all authors had agreed. In a second step, the first author discussed the allocation of the codes and the revision and expansion of the subcategories with the last author. Then all other authors verified the data analysis in various discussions. Topics of the discussions were, for example, to which categories data should be assigned to (e.g., strengths and weaknesses of randomisation could be assigned either to the main category process assessment or to scientific assessment). Our final agreement as to which main category data were assigned was led by the question "Which aspect of feasibility was most impacted?" Finally, all subcategories of the data were assembled and synthesised into one consistent

statement regarding the feasibility of the trial RCT, again following the objectives proposed by Thabane, et al. (9) and Tickle-Degnen(6).

To ensure credibility of our interpretations, we used peer debriefing with independent researchers at Umeå University and the Zurich University of Applied Sciences (ZHAW) who were not involved in the feasibility study as well as the member-check with the occupational therapists who participated in the study. Discussions with peers and occupational therapists included reflections on data collection, data analysis and organisation, structure of the findings and discussions, and possible limitations.

Findings and Discussion

In the following we will first present our findings and discuss the feasibility of the *process, resources, management*, and *scientific basis* of our trial RCT. Then we will reflect on some possible limitations and ethical aspects of the feasibility study.

Process Assessment

To assess the process, we evaluated recruitment, randomisation, retention rate, suitability of the inclusion criteria, and data collection methods. Between February 2011 and February 2012, 29 children were recruited. Overall, the recruitment rate within this 13 months period was very low. Reasons for this were various. There were difficulties with recruitment among different stakeholders. For example, paediatricians found recruitment for the study time consuming and the occupational therapists sought to influence randomisation after the children were recruited. More specifically, some occupational therapists advised parents not to participate, after initial recruitment, to avoid the risk of allocation of the children to the control group. In meetings with the paediatricians and the occupational therapists during the feasibility study, we reflected on the recruitment process, ethical issues (i.e., waiting time in the BA group), and possible strategies to enhance the recruitment rate. While this enabled us

to establish strong personal contacts with the recruiters, and their engagement in recruitment remained high, the issues with recruitment noted above prevailed.

Recruitment has been a problem in many trials (e.g., 3, 29) and is widely recognised as a challenge (30, 31). The resistance of stakeholders is often cited as a reason for low recruitment (e.g., 30, 32, 33, 34) supporting the results of our study. Watson and Torgerson (2006) suggested different strategies to improve recruitment rates, including personalized letters and telephone reminders (30). This feasibility study gave us a realistic picture of how long it would take to recruit an appropriate number of children for a larger RCT. Therefore, we can conclude that our results likely have high external validity because they mirror the real world of professional practice (35).

When we evaluated the randomisation done by independent persons, we found no problems with the allocation of the children to the AB or BA sequence. However, since enrolment of the children was sequential and the implementation of interventions unmasked, the randomisation might have been biased (36) (e.g., due to the fact that the intervening occupational therapist could anticipate to which group the next child would be assigned); this will need to be taken into consideration when selecting randomisation methods for the planned larger trial (37).

Out of the 29 children assessed to be eligible, 17 were included in the study. A flow of the children through the study is shown in *Figure 1*. Of the 12 who were excluded, two did not meet the diagnostic criteria, one moved to another country, and parents of nine eligible children declined to participate. The reasons for declining to participate were busy parent and child schedules, expenditure of time, non-acceptance of allocation to the control group, decline to wait with co-intervention (e.g., pharmacological or non-pharmacological such as speech therapy), and holidays.

Of the 17 children randomised and enrolled sequentially in the study, all attended baseline, post-tests, and 15 sessions of occupational therapy according to the study protocol, which is a retention rate of 100%. Given that we had a very low recruitment rate, we found the high retention rate interesting. We considered both the detailed description of the inclusion criteria (e.g., problems in ADL task performance based on parental report) and the comprehensive study protocol (e.g., the thorough description of every step) as reasons for the high retention rate. It is also likely that the parents and children who agreed to participate might have been especially motivated and therefore stayed in the study.

Evaluating the feasibility of the data collection process also included consideration of the use of two outcome measures. The occupational therapists reported no problems with the amount of time needed to complete them or with child burden with data collection procedures. This is likely because we had selected the outcome measures based on discussions with occupational therapists experienced in working with this client group. We specifically included assessments already known and widely used in Switzerland and we tried to keep the workload of the occupational therapists and burden for children acceptable. The problems that arose were related to the lack of adherence of the occupational therapists to the use of standardised administration procedures. While they all had experience in using the outcome measures before participating in the study, they had not been administereding them in a standardised manner (e.g., they had used an unstandardized version of the COPM or had modified the standardised ADL tasks included in the AMPS).

Earlier studies also describe the lack of commitment and adherence of therapists to the standardised use of outcome measures (34, 38). Reasons were various (e.g., refusal to implement standardised outcome measures because they were seen as too complicated (34), level of knowledge, and lack of time and experience (38). Bland and colleagues (2013) examined practitioner adherence to standardised administration of outcome measures across

settings and health professions and found that between 12% to 40% of the therapists did not follow the standardised testing procedures in practice. They also found that continuous support, feedback, and regular meetings had some impact on increasing adherence to the standardised use of outcome measures (39); they also were successful strategies in our study.

A common issue raised by the occupational therapists in our study was that the AMPS tasks "only were related to ADL". Moreover, many of the parents reported during the COPM interview that their child's problems also included performance of schoolwork tasks, play, and behaviour in the classroom or at home. The AMPS is, however, a test of quality of ADL task performance (19, 20). Thus, our findings may suggest a need to include other outcome measures (e.g., the School Version of the AMPS (40)), so as to be able to evaluate a wider range of occupational performance problems among children with mild disabilities. Because it is not possible to cover all aspects of occupational performance that may be of interest, it will be important to carefully select outcome measures that are in line with the study aim and the targeted outcomes. We decided to use only two outcome measures in order to keep children and occupational therapist burden low and to minimise dropout rates and bias. Obviously, we may need to reconsider our choices (e.g. by adding an observational assessment that add to the occupational therapists' burden, but not to that of the children).

To conclude, feasibility in relation to the process of the trial RCT was met in relation to the retention of children and the inclusion criteria. In the planned larger trial, changes need to be made in relation to the recruitment process, randomisation method, outcome measures, and data collection process.

Resources Assessment

We assessed resources needed for a larger RCT in relation to time, equipment, materials, and stakeholder's commitment to research. Our original time schedule for the

completion of the feasibility study needed to be extended from 12 to 20 months because we underestimated the time needed for a) initial training and ongoing communication with the occupational therapists, and b) communication with the paediatricians. While the occupational therapists were highly motivated and engaged in the training required as a basis for participating in the research project, the training was not sufficient to address the complexity inherent in implementing the study. For example, the occupational therapists did not know the basics about research (e.g., importance of a control group, process of randomisation) and wanted to influence the rigorous research process (e.g., random group allocation of participants). Consequently, some children withdrew from recruitment for the trial RCT (see *Figure 1*) and the time for completion of the study had to be extended in order to recruit further children. Many time-consuming discussions about the standardised administration procedures of the AMPS and the COPM and the documentation required by the study protocol also were necessary.

Our results are supported by earlier research that has also documented underestimation of time for communication with different stakeholders (e.g., 41). Conducting research in occupational therapy practice that involves diverse stakeholders requires additional time for thorough planning, continued communication, and supervision. Several studies have revealed that limited knowledge, skills, and commitment to conform a study protocol are barriers in research, which are a considerable threat to the overall attainment of the research goal (10, 34).

Perhaps because of the intensive discussions between the researchers and the nine intervening occupational therapists, the occupational therapists reported that their participation in our research project resulted in improvements in their evidence-based practice (EBP) skills in general and in relation to the use of standardised outcome measures specifically. Other studies have also shown improvements in EBP through participation in

research projects. Thomas and Law (42), for example, found that participation in research, adequate support, and research training were important factors that supported EBP.

The participating occupational therapists did not report any problems concerning space, equipment (e.g., cutlery in the kitchen), and materials (e.g., groceries for AMPS tasks). Therefore, we concluded that access to equipment and materials was feasible.

In summary, feasibility in relation to the resources of the trial RCT was good in relation to access to equipment and materials, but less in relation to the amount of time for training and on-going communication with stakeholders.

Management Assessment

We assessed management in relation to the competences and roles of the researchers in managing the trial RCT and to the occupational therapists' abilities to collect data and to adhere to the study protocol. Concerning our competencies and roles as researchers, we identified the following challenges: the role of the novice researcher and the geographical distribution of the research team (i.e., Switzerland, Sweden, USA). However, our strength was the combination of diverse expertise in translational research, assessment and intervention, and rigour in planning and implementing the efficacy studies based on international standards for RCTs (12, 13). This combination of different competences is generally recommended (41).

Adherence to the intervention protocol was feasible concerning the completion of the COPM and AMPS evaluations, scoring the AMPS, and completion of required documentation. Despite the challenges concerning the above mentioned use of standardised outcome measures, the occupational therapists fully adhered to the planned intervention process as described in the study protocol. The provision of a detailed study protocol, training, and regular meetings seemed to establish adherence. This is in line with Hammel et

al. (43), who recommend initial training and on-going supervision in order to ensure adherence to complex interventions. As mentioned earlier, challenges of data collection included following standardised testing procedures and documenting results completely, which indicate the need for evaluating and supporting the documentation procedures in the beginning of the study (e.g., after three cases) and regularly during the study (e.g., evaluate completeness of documentation in every phase).

In conclusion, the management of the trial RCT was judged to be feasible in relation to the researchers' competences, roles, completion of data collection, scoring the AMPS, adherence to the study protocol, and completion of the required documentation. The management of and support to implement assessments in a standardised way, however, did not seem adequate and needs reconsideration. The adherence to the study protocol was feasible concerning completion of the COPM and AMPS evaluations, scoring of the AMPS, and completion of required documentation.

Scientific Basis Assessment

We assessed the scientific basis of the trial RCT by evaluating the completeness and feasibility of the study protocol, the definition of the criteria for clinical meaningfulness, and the appropriateness of the research design. The occupational therapists reported that they found the study protocol that was provided by the researchers very helpful because it gave them a complete and comprehensive description of what was expected of them. They could easily adhere to it. Therefore, we concluded that the provided study protocol, based on the general occupational therapy program based on the OTIPM, was a helpful tool that should be included in a subsequent larger RCT. Only a small group of occupational therapists changed the design of the standardised documentation sheet because it differed in appearance from their usual documentation sheets. That did not have an impact on data analysis, but it did affect negatively on the time the researchers needed to extract the data.

The definition of clinical meaningfulness of our two outcome measures has been described in existing literature: for the AMPS, a clinically meaningful change between two individual measures is 0.3 logits on both scales (20). For the COPM, a clinically meaningful change between two individual measures is 2 points for perceived quality of performance and perceived satisfaction (18). We evaluated appropriateness of these criteria for our context. Out of 17 children, nine changed by at least than 0.3 logits on at least one of the two AMPS scales (i.e., ADL motor and/or ADL process) during intervention. All children changed by more than 2 points on one of the COPM scales. We did not find any patterns related to diagnoses, gender, age, or group allocation in terms of those who changed and those who did not. Therefore, we conclude that the AMPS and the COPM are likely sensitive enough to detect changes in a larger study.

Finally, yet importantly, we assessed the appropriateness of the crossover RCT design for occupational therapy intervention studies. Based on the problems that we described earlier (e.g., adherence to the process of randomisation) we question, as have other authors (e.g., 1), the appropriateness and relevance of RCTs. Practical clinical trials (PCTs) or multi-centre trials where centres (not participants) are randomised are possible alternatives that have been recommended (2, 44). In contrast to RCTs, PCTs focus more on contextual issues, include heterogeneous clients in multiple and diverse settings, use multiple outcome measures (including quality of life and costs), and compare interventions that are closer and more relevant to real practice settings (44). In our trial RCT, on the one hand, we implemented interventions that were close to real practice settings; on the other hand we implemented procedures (e.g., randomisation) and outcomes that where not common in practice settings. Some of the problems that we encountered might have been due to our use of an RCT design. Therefore, we are considering using a PCT for our larger study. We also are considering

including a control group that receives the occupational therapy group interventions and parent education .

In summary, the description of the study protocol and the criteria for clinically meaningfulness were met; feasibility concerning the research design was not met. Consideration will need to be given to our choice of research design.

Limitations

We analysed our data based on the principles of content analysis, using the objectives of feasibility studies as main categories, thus, proceeding in a manner that was primarily deductive. Given that qualitative research is commonly inductive, meaning that categories emerge from that data (45), one could question our approach. We chose this approach because we saw the advantage of having predefined categories guiding our analysis.

We were not able to involve children or parents in the evaluation of feasibility due to limitation in resources, resulting in their views not contributing to refining the study. For example their experiences and opinions might possibly have pointed to further aspects of the process that would need reconsideration in a larger study.

Another limitation is that we used qualitative data based on the minutes of meetings between researchers, paediatricians, and occupational therapists, minutes of telephone meetings, e-mails, documentation of outcomes and intervention, and field notes, but we did not collect data based on individual or focus group interviews. Such interviews might have been helpful for further interpretation of the data in relation to the feasibility of the trial RCT.

Moreover, the authors evaluated feasibility mainly from the researchers' perspective, using peer debriefing and member checking for establishing credibility. An evaluation of feasibility from an outsider's perspective might have been more objective and might have revealed other aspects of feasibility.

Ethical Considerations

Children are a considered to be a group of vulnerable persons (46). Therefore, we put close attention to specific ethical issues in research with children: first, we obtained informed consent from both the parents and the children. Furthermore, we implemented a feasibility study of a planned larger RCT with cross-over design to ensure that every child received the same occupational therapy intervention. In order to minimize outside influences and manipulation, we openly accounted for our purposes and methods, and registered the study at the International Standard Randomized Controlled Trial Number Register (ISRCTN).

Conclusion

We implemented a feasibility study to assess the process, resources, management, and scientific basis to gain and provide information for a subsequent larger planned RCT. Based on the findings of the current study, we suggest the following modifications to our future larger study.

- The results of the process assessment indicated a need for modification of a) the recruitment process to improve recruitment rate, for example by establishing strong contacts with paediatricians who recruit the participants and contacting potential participants in a personalised way (e.g., personalised letters); b) the methods used for randomisation to ensure that it is valid; and c) the outcome measures, for example by addressing the need to include other outcome measures that can be used to evaluate a wider range of occupational performance problems among children with ADHD and/or DCD (e.g., social behaviour, performance of schoolwork tasks).

- The results of the resources assessment indicated a need for additional time for training the participating occupational therapists and developing their experience, knowledge, and skills in EBP. Additional training in the basics of research will likely support their implementation of standardised testing procedures.

- The results of the scientific basis assessment indicated that a) the AMPS and COPM likely will be sufficiently sensitive to detect changes in a subsequent larger trial, and b) possible alternatives to the planned RCT design, for example a PCT design or a multi-centre study, may need to be considered when finalising the plan for the larger study.

Based on our findings of the feasibility study, we will refine the methods and procedures of the planned larger trial. This feasibility study was useful for assessing methods and procedures of an RCT, and it serves as a basis for refining the research plan.

At the same time, we found it challenging to describe concisely the results of our feasibility study because there are no official guidelines for framing feasibility studies. We used two frameworks structuring our manuscript: the CONSORT guidelines of non-pharmacologic RCTs (12, 13) and feasibility objectives based on the work of Thabane et al. (9) and Tickle-Degnen (6). For our study context and our aims, these frameworks were very helpful. However, we appreciated that for other contexts and study aims, different frameworks might be more suitable.

Competing Interests of all Authors

The authors declare no competing interests.

Acknowledgements

The authors especially thank all children, their parents, and occupational therapists, who participated in this study, especially Susanne Rönnfeld, who coordinated the work of occupational therapist practitioners. Furthermore, we thank Barbara Aegler for her contribution as the blinded AMPS rater, André Meichtry for his statistical expertise and support, and Linda Tickle-Degnen for sharing with us her expert advice related to feasibility studies and RCTs. Moreover, we thank our colleagues at Umeå University and the ZHAW

who were involved in peer debriefing, especially Magnus Zingmark and Ellinor Larson for their continuous and enriching support.

This study was funded by the Swiss National Science Foundation (Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung DORE-Förderinstrument für praxisorientierte Forschung 13DPD6-127161) and supported by the Austrian, German, and Swiss Associations of Occupational Therapy (Ergotherapie Austria, Deutscher Verband der Ergotherapeuten E. V. and ErgotherapeutInnen Verband Schweiz), as well as by an internal grant of the School of Health Professions at the ZHAW.

References

1. Glasgow RE. Translating research to practice: Lessons learned, areas for improvement, and future directions. Diab care. 2003;26:2451-6.
2. Tunis SR, Stryer DB, Clancy CM. Practical clinical trials: Increasing the value of clinical research for decision making in clinical and health policy. J Med Am Med Ass. 2003;290:1624-32.
3. Leemrijse C, Meijer OG, Vermeer A, Ader HJ, Diemel S. The efficacy of Le Bon Depart and Sensory Integration treatment for children with developmental coordination disorder: A randomized study with six single cases. Clinic Rehabil. 2000;14:247-59.
4. Glasgow RE, Lichtenstein E, Marcus AC. Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. American journal of public health. 2003;93:1261-7.
5. Glasgow RE. What does it mean to be pragmatic? Pragmatic methods, measures, and models to facilitate research translation. Health Educ Behav. 2013;40:257-65.
6. Tickle-Degnen L. Nuts and bolts of conducting feasibility studies. Am J Occup Ther. 2013;67:171-6.
7. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. J Psychiatr Res. 2011;45:626-9.
8. National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre. NIHR evaluation, trials and studies coordination centre: Glossary Southampton: Universtiy of Southampton; 2011 [06.06.2013]. Available from: http://www.netscc.ac.uk/glossary/#glos6.
9. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, et al. A tutorial on pilot studies: the what, why and how. BMC Med Res Methodol. 2010;10:1-10.
10. Gardner G, Gardner A, MacLellan L, Osborne S. Reconceptualising the objectives of a pilot study for clinical research. Int J Nurs Stud. 2003;40:719-24.
11. Mayring P. Qualitative Inhaltsanalyse. Grundlagen und Techniken [Qualitative content analysis. Basics and techniques]. 11th ed. Weinheim und Basel: Beltz Verlag; 2010.
12. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Methods and processes of the CONSORT group: Example of an extension for trials assessing nonpharmacologic treatments. Ann Intern Med. 2008;148:60-6.
13. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. Br Med J. 2010;340:c869:1-28.
14. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, text revision (DSM-IV-TR). Fourth ed. Arlinton: Author; 2000.
15. Fisher AG. Occupational Therapy Intervention Process Model: A model for planning and implementing top-down, client-centered, and occupation-based interventions. Fort Collins: Three Star Press; 2009.
16. Fisher AG. Occupation-centred, occupation-based, occupation-focused: Same, same or different? Scan J Occup Ther. 2013;20:162-73.
17. Simmons CD, Griswold LA. Using the Evaluation of Social Interaction in a community-based program for persons with traumatic brain injury. Scan J Occup Ther. 2010;17:49-56.
18. Law M, Baptiste S, Carswell A, McColl MA, Polatajko HJ, Pollock N. COPM. Canadian Occupational Performance Measure. 4th ed. Idstein: Schulz-Kirchner Verlag GmbH; 2009.
19. Fisher AG, Jones KB. Assessment of Motor and Process Skills: User manual. 7th Revised ed: Three Star Press; 2012.

20. Fisher AG, Jones KB. Assessment of Motor and Process Skills: Development, standardization, and administration manual. 7th Revised ed: Three Star Press; 2012.
21. Fisher AG, Griswold LA. Performance Skills. Implementing Performance Analyses to Evaluate the Quality of Occupational Performance. In: Schell BB, Gillen G, Scaffa M, Cohn E, editors. Willard & Spackman's Occupational Therapy. 12th ed: Lippincott Williams & Wilkins; 2014. p. 1-44.
22. Fisher AG, Merritt BK. Current standardization sample, item and task calibration values, and validity and reliability of the AMPS. In: Fisher AG, Jones KB, editors. Assessment of Motor and Process Skills Vol 1: Development, standardization, and administration manual 1. 7th Revised ed. Fort Collins: Three Star Press; 2012. p. 15-1--82.
23. Gantschnig BE, Page J, Nilsson I, Fisher AG. Detecting differences in activities of daily living between children with and without mild disabilities. Am J Occup Ther. 2013;67:319-27.
24. Gantschnig BE, Page J, Fisher AG. Cross-regional validity of the Assessment of Motor and Process Skills (AMPS) for use in Middle Europe. J Rehabil Med. 2012;44:151-7.
25. Tam C, Teachman G, Wright V. Paediatric Application of Individualised Client-Centred Outcome Measures: a Literature Review. Br J Occup Ther. 2008;71:286-96.
26. Cusick A, Lannin NA, Lowe K. Adapting the Canadian Occupational Performance Measure for use in a paediatric clinical trial. Disabil Rehabil. 2007;29:761-6.
27. Verkerk GJ, Wolf MJM, Louwers AM, Meester-Delver A, Nollet F. The reproducibility and validity of the Canadian Occupational Performance Measure in parents of children with disabilities. Clinical Rehabilitation. 2006;20:980-8.
28. Polit DF, Beck CT. Nursing research: Generating and assessing evidence for nursing practice. 8th ed. Philadelphia: Lippincott Williams & Wilkins; 2008.
29. Warner ET, Glasgow RE, Emmons KM, Bennett GG, Askew S, Rosner B, et al. Recruitment and retention of participants in a pragmatic randomized intervention trial at three community health clinics: results and lessons learned. BMC public health. 2013;13:192.
30. Watson JM, Torgerson DJ. Increasing recruitment to randomised trials: a review of randomised controlled trials. BMC Med Res Methodol. 2006;6:34-9.
31. Mapstone J, Elbourne D, Roberts I. Strategies to improve recruitment to research studies. Cochrane Database Systematic Reviews. 2007;18:MR000013.
32. Hegel MT, Lyons KD, Hull JG, Kaufman P, Urquhart L, Li Z, et al. Feasibility study of a randomized controlled trial of a telephone-delivered problem-solving-occupational therapy intervention to reduce participation restrictions in rural breast cancer survivors undergoing chemotherapy. Psycho-Oncology. 2011;20:1092-101.
33. Jackson J, Mandel D, Blanchard J, Carlson M, Cherry B, Azen S, et al. Confronting challenges in intervention research with ethnically diverse older adults: the USC Well Elderly II Trial. Clinical Trials. 2009;6:90-101.
34. Fange A, Risser R, Iwarsson S. Challenges in implementation of research methodology in community-based occupational therapy: the Housing Enabler example. Scan J Occup Ther. 2007;14:54-62.
35. Tomlin G, Borgetto B. Research Pyramid: A New Evidence-Based Practice Model for Occupational Therapy. Am J Occup Ther. 2011;65(2):189-96.
36. Grant WC, Anstrom KJ. Minimizing selection bias in randomized trials: A Nash equilibrium approach to optimal randomization. Journal of Economic Behavior & Organization. 2008;66(3–4):606-24.
37. Berger V, Exner D. Detecting selection bias in randomized clinical trials. Control Clin Trials. 1999;20:319 - 27.
38. Kjellberg A, Bolic V, Haglund L. Utilization of an ICF-based assessment from occupational therapists' perspectives. Scan J Occup Ther. 2012;19:274-81.
39. Bland MD, Sturmoski A, Whitson M, Harris H, Connor LT, Fucetola R, et al. Clinician adherence to a standardized assessment battery across settings and disciplines in a poststroke rehabilitationpopulation. Arch Phys Med Rehabil. 2013;94:1048-53.
40. Fisher AG, Bryze K, Hume V, Griswold LA. School AMPS: School version of the Assessment of Motor and Process Skills. 2nd ed. Ft. Collins: Three Star Press; 2007.
41. Choi BC, Pak AW. Multidisciplinarity, interdisciplinarity, and transdisciplinarity in health research, services, education and policy: 2. Promotors, barriers, and strategies of enhancement. Clinical and investigative medicine Medecine clinique et experimentale. 2007;30:E224-32.
42. Thomas A, Law M. Research utilization and evidence-based practice in occupational therapy: A scoping study. Am J Occup Ther. 2013;67:e55-e65.
43. Hammell KR, Miller WC, Forwell SJ, Forman BE, Jacobsen BA. Sharing the agenda: Pondering the politics and practices of occupational therapy research. Scan J Occup Ther. 2012;19:297-304.
44. Glasgow RE, Magid DJ, Beck A, Ritzwoller D, Estabrooks PA. Practical clinical trials for translating research to practice: design and measurement recommendations. Med Care. 2005;43:551-7.
45. Schreier M. Qualitative content analysis in practice. London: SAGE Publications; 2012.
46. Brody BA. The Ethics of biomedical research: An international perspective. Oxford: Oxford University Press; 1998.

Table 1
Main and Specific Objectives for Evaluating the Feasibility of the Trial RCT

	Main Feasibility Objectives			
Main Objectives	Process assessment	Resources assessment	Management assessment	Scientific basis assessment
Specific Feasibility Objectives	To evaluate • Recruitment, randomisation and retention • Suitability of inclusion criteria • Appropriateness of outcome measures and data collection methods	To evaluate • Required time, equipment and material • Stakeholders commitment to research	To evaluate • Researchers strengths and shortcomings in managing the project • Necessity of additional regional or international experts • Documentation according to the study protocol	To evaluate • Completeness and feasibility of the study protocol • Appropriateness of research design for the specific setting and context • Criteria for statistical and clinical significance

Note. The main and specific objectives are based on objectives of feasibility studies recommended by Thabane et al. (9) and Tickle-Degnen (6).

Table 2
Demographic Data: Age, Gender, Diagnosis, and Characteristics of the Children and Occupational Therapists, Who Implemented the Interventions and Evaluations

		Intervention	Control	Total
Children (Trial RCT Participants)	Age *M,(SD),*[Range]	6.6, (1.7), [5-9]	7.5, (1.0), [6-9]	7.1, (1.4), [5-9]
	Gender (Girls, Boys)	2, 6	4, 5	6, 11
	Diagnoses (ADHD, DCD, Both)	2, 5, 1	3, 4, 2	5, 9, 3
Occupational Therapists (Feasibility Study Participants)	Age, *M, (SD),* [Range]			43.4 (8.3), [30-55]
	Gender (Female, Male)			9, 1
	Clinical experience in years *M, (SD),* [Range]			14.3, (6.1), [7-26]

Table 3
Overview Over Main Categories and Subcategories of the Content Analysis

Main category	Subcategories
Process assesment	• Low recruitment rate and difficulties in randomisation • High retention rate • Appropriate inclusion criteria • Challenging data collection
Resources assessment	• Lack of time for training and communication with participants, supervision during the process, implementing new methods in a specific region • Smooth access to equipment and material • Questionable commitment to research
Management assessment	• Various competences within research team in managing research in a challenging context • Complete and timely data collection and adherent implementation and documentation of intervention.
Scientific basis assessment	• Detailed study protocol • Disputable criteria clinical meaningfulness • Inappropriate research design

Note. The main categories are the objectives of feasibility studies recommended by Thabane, et al. [9] and Tickle-Degnen [6]. The subcategories are based on the specific feasibility objectives [6,9] revised and expanded by going back and forth between theory and data.